K112945

NOV - 3 2011

September 30, 2011

Contact Information

Ryan Goosen
President
Phone: 616-301-7800, ext. 105
Fax: 616-301-7799
E-mail: rgoosen@inrad-inc.com

Company Information

Inrad, Inc
4375 Donker Court SE
Kentwood, MI 49512
Phone: 616-301-7800
Fax: 616-301-7799

Device Name(s)

EliteCore™ Full Core Biopsy Device
EliteCore™ Full Core Biopsy Device w/HiLiter®

Device Summary

Trade or Proprietary Name:	EliteCore™ Full Core Biopsy Device EliteCore™ Full Core Biopsy Device w/HiLiter®
Common or Usual Name:	Biopsy Instrument
Classification Name:	Gastroenterology-urology biopsy instrument (21 CFR 876.1075, Product code KNW)

Name of Predicate(s) or Legally Marketed Device(s)

K090611– Revolution® Full Core Biopsy Device

K112945

SECTION 5: 510(k) SUMMARY

Device Description

The EliteCore™ Full Core Biopsy Device is a sterile, disposable device which features a stainless steel cutting cannula with spoon, rotating coring cannula and stylet. The device is comprised of a plastic housing that contains the mechanically actuated components. The key performance attribute of the EliteCore™ Full Core Biopsy Device is the capability of obtaining a full core specimen. A variable throw feature allows the user to choose a throw setting ranging from 13 to 25 mm.

Indications for Use

The device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.

Substantial Equivalence

The EliteCore™ Full Core Biopsy Device has the same intended use as the Revolution® Full Core Biopsy Device with the exception of the omission of the word breast. The device and the predicate device have the same technological characteristics in terms of design and materials.

Performance Testing Summary

Performance testing confirms that the quality of samples obtained with the EliteCore™ Full Core Biopsy Device is equivalent to that of the predicate device as shown below:

Test	Involved	How Equivalent
-Package inspection	Visually inspect packaging for damage, loose components tip protector secure, and variable throw set at 22mm.	Identical testing performed on predicate device w/ equivalent results.
-Burst test	Measure pressure at which sealed tray fails.	Identical testing performed on predicate device w/ equivalent results.
-Device inspection	Visually inspect device for damage	Identical testing performed on predicate device w/ equivalent results.

-Dimensional	Measure variable throw desired vs. actual.	Identical testing performed on predicate device w/ equivalent results.
	Measure variable throw after dry fires, desired vs. actual.	Identical testing performed on predicate device w/ equivalent results.
	Measure force to fire front triggers (RH / LH)	Identical testing performed on predicate device w/ equivalent results.
	Measure force to fire rear trigger.	Additional testing that was not performed on predicate.
-Tissue test	Able to take tissue sample in chicken and liver.	Identical testing performed on predicate device w/ equivalent results.
-Tissue test cont.	Able to take tissue samples at various throw distances.	Identical testing performed on predicate device w/ equivalent results.
	Measure 1st sample as compared to last sample for sample weight and verify no loss of effectiveness.	Identical testing performed on predicate device w/ equivalent results.
	Mates with adjustable coaxial And able to take sample.	Identical testing performed on predicate

		device w/ equivalent results.
-Verify weld integrity	Visually inspect device for damage along weld joints after functional testing.	Identical testing. performed on predicate device w/ equivalent results.
-Dimensional	Measure cannula, spoon, and stylet for migration.	Identical testing performed on predicate device w/ equivalent results.
	Measure the joint strength for the cannula, spoon, and stylet.	Identical testing performed on predicate device w/ equivalent results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Ryan Goosen
President
Inrad Inc.
4375 Donker CT SE
GRAND RAPIDS MI 49512

NOV - 3 2011

Re: K112945
Trade/Device Name: EliteCore™ Full Core Biopsy Device
EliteCore™ Full Core Biopsy Device w/HiLiter®
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: September 30, 2011
Received: October 4, 2011

Dear Mr. Goosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112945

Device Name: EliteCore™ Full Core Biopsy Device
EliteCore™ Full Core Biopsy Device w/HiLiter®

Indications for Use: The device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112945